

## PATENT

## In the UNITED STATES PATENT and TRADEMARK OFFICE

APPLICANT: Wolf, et al.	EXAMINER: Choi, F.
SERIAL NO.: 09/524,716	ART UNIT: 1616
FILING DATE: March 14, 2000	DOCKET NO.: 6671.US.O1
<p>I hereby certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Assistant Commissioner for Patents, Washington, D.C., 20231, on the date shown below.</p> <p><u>Sarah Mayhew</u> <u>10/26/01</u></p> <p>Sarah Mayhew Date</p>	

Assistant Commissioner for Patents  
Washington, D.C. 20231

REMARKS

This paper follows the Office Action mailed June 27, 2001 and is accompanied by a request for a 1-month extension of time. Claims 1-24 remain active in this application. As requested, the cross reference section has been updated to include the U.S. patent number and issue date of the co-pending application. The Examiner has requested information confirming that the cross reference update does not constitute new matter. After discussions with Patent Agent Parlet, Examiner Pratt issued an Examiner's Amendment for U.S. Patent 6,248,375 in which "and Method of Using" was added to the title at filing, "Diabetic Nutritionals", thereby more completely describing the claimed invention.

This invention relates to a carbohydrate mixture that blunts the postprandial glycemic response of digestible glucose polymers. The carbohydrate mixture is optionally admixed with nonabsorbent carbohydrates, fiber and indigestible oligosaccharides to form a carbohydrate system for diabetics. Additionally, the invention relates to nutritional formulas that incorporate the carbohydrate mixture or the carbohydrate system. Further, this invention relates to a method of delivering nutrition to an individual with diabetes by feeding said nutritional formulas.

Claims 1-24 have been rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1,2,6,9 and 23 have been amended by removing the "two component" descriptor of the carbohydrate mixture, thereby removing any confusion that may occur when the carbohydrate system

contains more than two components. Support for this amendment may be found in Table 2 on page 8; page 11, line 17; page 12, line 31; and page 13, line 21 of the specification.

Claims 1-5 have been rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under U.S.C. 103(a) as obvious over Hicks et al. Hicks et al. found that high fructose corn syrup could be used in place of sucrose to cure ham. The claimed carbohydrate mixture requires fructose and at least one digestible glucose polymer source. Hicks does not teach the use of an additional digestible glucose polymer in the curing of ham. As described on page 6 lines 10-15, the Applicants discovered that the use of the fructose in the carbohydrate mixture significantly decreases the glycemic response of glucose polymers when compared to the glucose polymer alone. One knowledgeable in the art would not find in Hicks a suggestion that using fructose to cure ham would in any way affect the glycemic response of a diabetic.

Claims 1-17, 20, 21, 23 and 24 have been rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under U.S.C. 103(a) as obvious over Kaufman. Kaufman teaches the use of a carbohydrate system containing a slowly absorbed complex carbohydrate from 10 to 30% of the carbohydrate system, a rapidly absorbed complex carbohydrate from 14 to 40% of the carbohydrate system and a simple sugar from 0 to 30% of the carbohydrate system as a sweetening agent. A therapeutic food including this carbohydrate system diminishes the fluctuations in blood sugar levels and prevents hypoglycemic episodes in diabetics. Kaufman further limits the use of simple sugar component (other than fructose) to less than 6% of the total carbohydrate system. The Kaufman carbohydrate system requires three components: slowly absorbed complex carbohydrate, a rapidly absorbed complex carbohydrate and a simple sugar as a sweetening agent.

The claimed carbohydrate mixture includes from 5 to 50 % of the carbohydrate mixture as a source of fructose in combination with at least one source of readily digestible glucose polymers making up 50 to 95% of the carbohydrate mixture. Readily digestible glucose polymers (a.k.a. Kaufman's rapidly absorbed complex carbohydrate) are defined as rapidly digested hydrolyzed starches and glucose oligomers (page 7, line 5). The claimed carbohydrate system of the instant invention does not require the slowly absorbed complex carbohydrate. Yet the claimed carbohydrate system results in the same effect as the Kaufman carbohydrate system. An unexpected advantage of the claimed carbohydrate system is that a nutritional formula may contain a higher percentage of rapidly digested carbohydrates, which are typically limited in a diabetics diet, and produce a lower glycemic response than expected. This is exemplified by the presence of readily digestible glucose polymers at 50 to 95% of the

carbohydrate system, while Kaufman limits the rapidly absorbed complex carbohydrate component to 14 to 40% of the carbohydrate system. Further, the optional indigestible oligosaccharides and nonabsorbent carbohydrates of the claimed carbohydrate system are resistant to endogenous digestion therefore do not meet the definition of Kaufman's slowly absorbed complex carbohydrates (page 8, lines 1-10).

Claims 2-24 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S Patent No. 6,248,375 in view of Kaufman. A terminal disclaimer is attached thereby rendering this rejection moot.

In light of the foregoing, Applicant respectfully requests examination and allowance of the currently pending claims. Applicant request the Examiner to contact Applicant's Representative below, if doing so may expedite disposition of this case.

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## **Redline version of the amendments**

In the specification:

This application is related to [the Diabetic Nutritionals application] U.S. Patent # 6,248,375, issued June 19, 2001, filed concurrently herewith by Gilles et al., the contents of which are hereby incorporated by reference.

In the claims:

1.(amended) A [two component] carbohydrate mixture suitable for incorporation into an enteral nutritional comprising:

- a) a source of fructose from about 5 wt/wt% to about 50 wt/wt% of the [two component] carbohydrate mixture: and
- b) at least one digestible glucose polymer source from about 50 wt/wt% to about 95 wt/wt% of the [two component] carbohydrate mixture.

2.(amended) A carbohydrate system suitable for incorporation into an enteral nutritional comprising:

- a) at least about 43 wt/wt% of said carbohydrate system is the [two component] carbohydrate mixture of claim 1; and
- b) less than about 57 wt/wt% of said carbohydrate system is nutrients selected from the group consisting of nonabsorbent carbohydrates, dietary fiber and indigestible oligosaccharides.

6.(amended) A nutritional product comprising:

- a) a [two component] carbohydrate mixture comprising from about 25% to about 60% of the total calories of the product, said [two component] carbohydrate mixture comprising:
  - i) a source of fructose from about 5 wt/wt% to about 50 wt/wt% of the [two component] carbohydrate mixture: and

- ii) at least one digestible glucose polymer source from about 50 wt/wt% to about 95 wt/wt% of the [two component] carbohydrate mixture,
- b) a source of fat comprising less than about 37% of the total calories of the product; and
- c) a source of protein comprising from about 10% to about 35% of the total calories of the product.

9.(amended) The nutritional product of claim 6 wherein the [two component] carbohydrate mixture comprises from about 35% to about 55% of the total calories of the product.

23. (amended) A method for blunting the postprandial glycemic response comprising enterally administering the [two component] carbohydrate mixture according to claim 1.